

Saving and Reopening SPL Documents Using SPL Xforms

Basic instructions for using SPL
Xforms to save and revise
SPL documents.

Version 1.0

Saving SPL Xforms

Saving SPL Xforms

HL7 SPL - Drug Listing v 1.01	
<input type="button" value="Open"/> <input type="button" value="Save As"/> <input type="button" value="Save"/>	
Document Information <input type="button" value="Drug Listing"/> <input type="button" value="Content of Labeling"/> <input type="button" value="Preview"/>	
Document Information	
Type of document	HUMAN PRESCRIPTION DRUG LABEL <input type="button" value="v"/>
ID	be53012a-c0d2-44e2-84a6-1bf6280d74a1
Set ID	1997ed60-2a04-4edf-a5d0-ba23208277ba
Version Number	1
Effective Time	20090824

- View data in fields to ensure accuracy and completeness

Saving the SPL Document

HL7 SPL - Drug Listing v 1.01

Open Save As Save

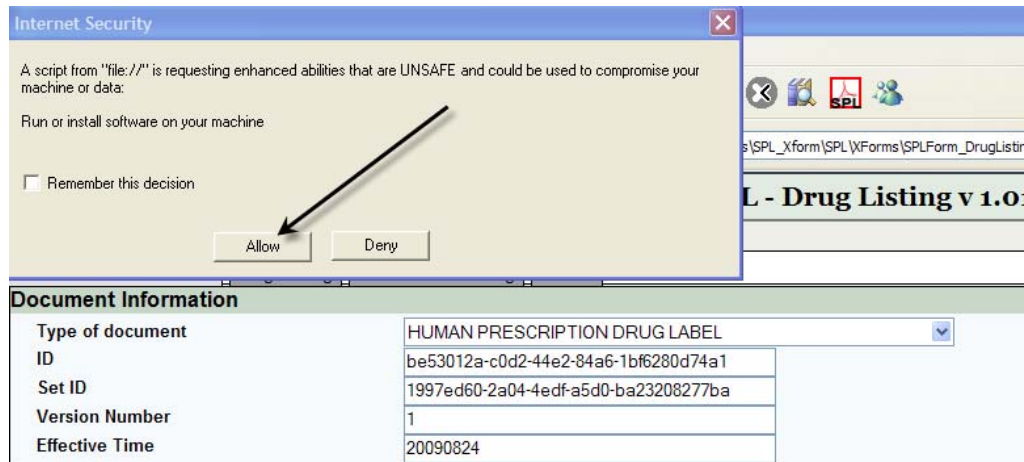
Document Information Drug Listing Content of Labeling Preview

Document Information

Type of document	HUMAN PRESCRIPTION DRUG LABEL
ID	be53012a-c0d2-44e2-84a6-1bf6280d74a1
Set ID	1997ed60-2a04-4edf-a5d0-ba23208277ba
Version Number	1
Effective Time	20090824

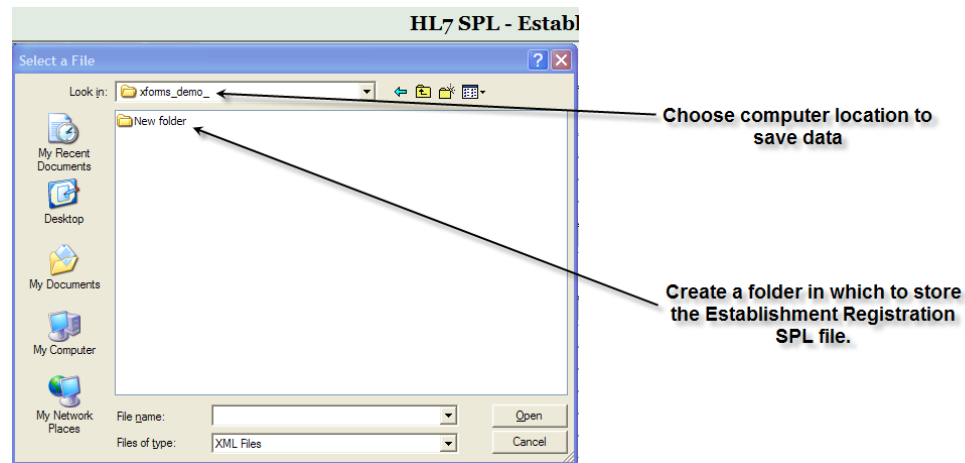
- When saving an SPL document for the first time, click the “Save As” button.
- If you select the “Save” button to save document for the first time, you will not save the document.

Security Prompt



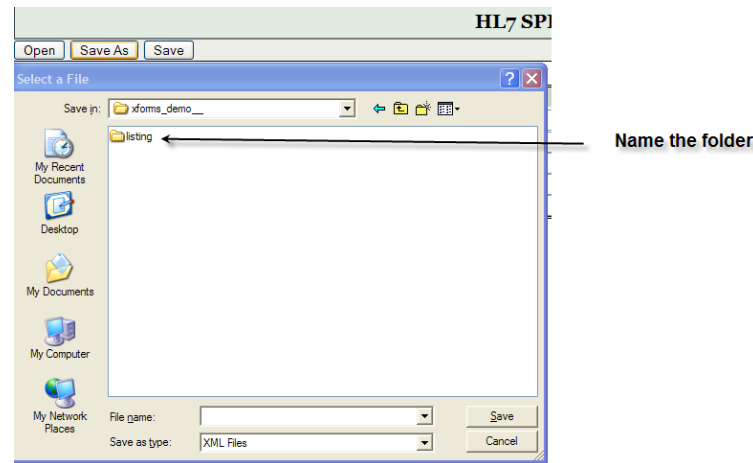
- Select “Allow” to continue saving the document after reviewing the security message.
- To avoid this message in future, check the “Remember This Decision” check box.

Creating the Submission Folder



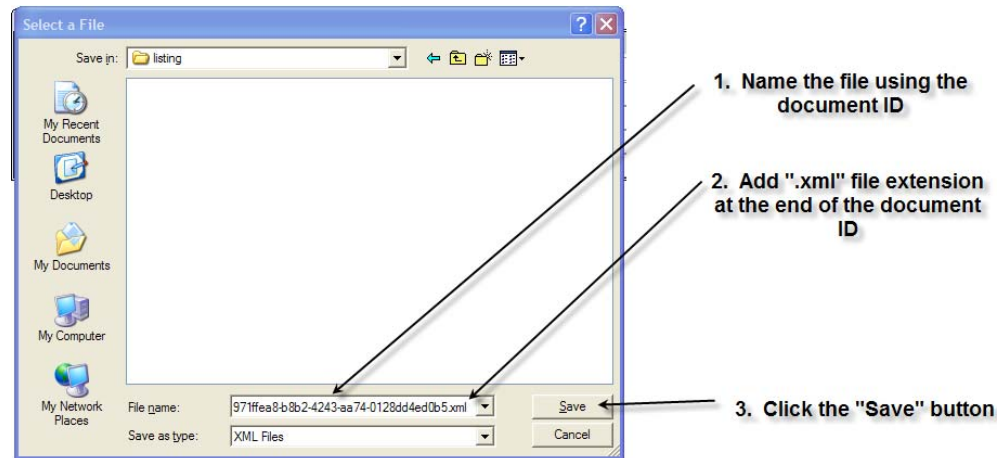
- Choose computer location in which to store folder to contain the SPL file.
- Create a folder in which to store the listing SPL file.
- Only add one SPL document per folder.
- Click folder to open.

Naming the Submission Folder



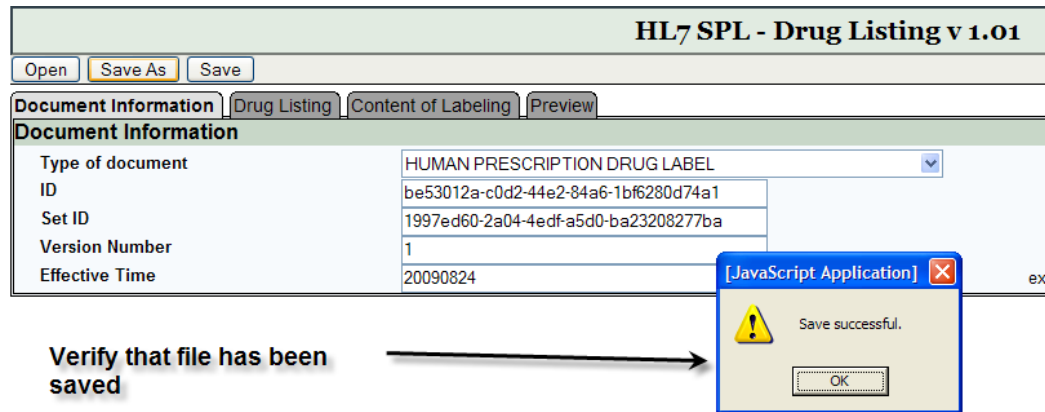
- There is no folder naming convention
- However, we recommend that you not use symbols in the name of the folder.

Naming the SPL File



- Use the **document ID** (GUID) as the document file name
- Use “.xml” as the file extension
- Choose “Save” button
- If you do not follow these steps your SPL will **FAIL** validation.

Saving the File cont...



- If save action was successful, “Save Successful” prompt should display.

Reopening SPL Documents for Review or Revision

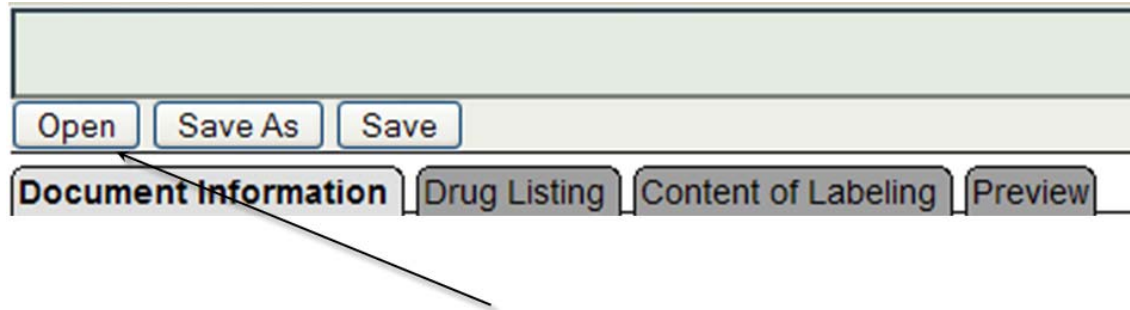
Open SPL Xforms

The screenshot displays a web-based interface titled "HL7 SPL - Drug Listing v". At the top, there are three buttons: "Open", "Save As", and "Save". Below these is a tabbed interface with four tabs: "Document Information", "Drug Listing", "Content of Labeling", and "Preview". The "Document Information" tab is currently selected. This tab contains a form with the following fields:

Document Information	
Type of document	<input type="text" value=""/>
ID	<input type="text" value=""/>
Set ID	<input type="text" value=""/>
Version Number	<input type="text" value=""/>
Effective Time	<input type="text" value=""/>

- Open SPL xforms which was used to create the SPL document
- Ensure that the type of SPL Xforms is the same as the type of SPL file you are attempting to open.

Selecting Open Button



Select the "Open" button

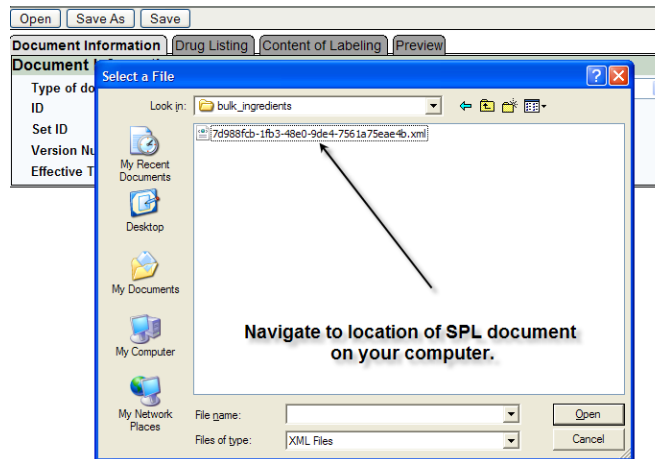
- Click the “Open” button to begin “file opening” process.

Security Prompt



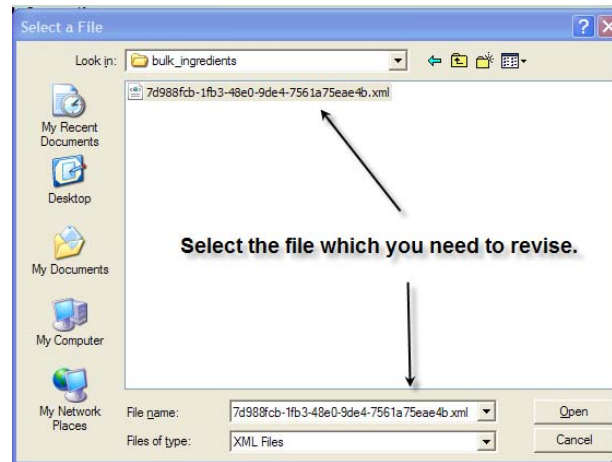
- Select “Allow” to continue saving the document after reviewing the security message.
- To avoid this message in future, check the “Remember This Decision” check box.

Navigating to SPL Location



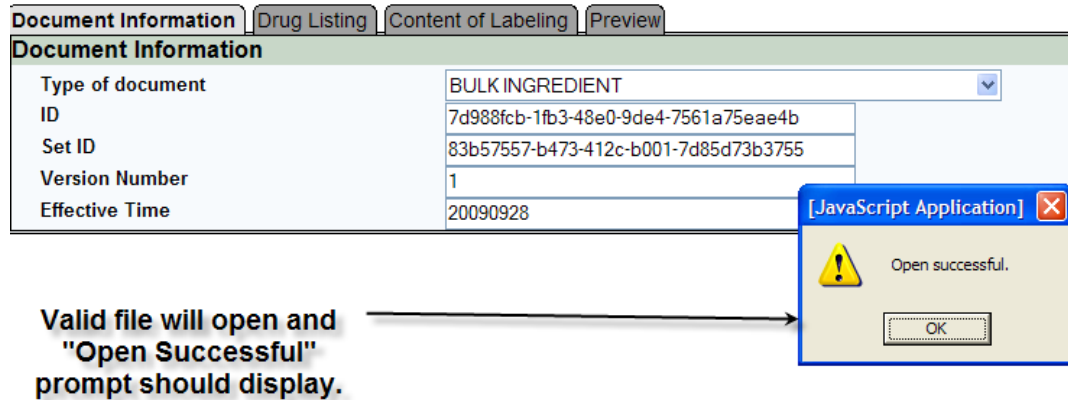
- Determine location of SPL document.
- Navigate to location of SPL document

Selecting File to Open



- Using computer mouse, select the file to be opened for revision or review.

Opening File cont...



- If opening of the file was successful, "Open Successful" prompt will display.

Notes

- Ensure that SPL file has the file extension “.xml” before saving or reopening SPL documents.
- Ensure that file extension is in lower case letters.
- SPL R3 documents can not be edited via the SPL R4 Xforms.
- Invalid SPL R4 files may not be editable via the SPL R4 files.

Test Your SPL R4 Submissions

- Use Pragmatic Data Validator Lite to test your SPL files prior to transmission to FDA:
<http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>
- NOTE
 - This validator tool is **NOT** connected to FDA database.
 - This tool assist you in detection of 90 – 95% of technical errors in SPL documents.

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov URL. Below this is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories: Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a sign-up link for email updates, a paragraph describing the council's role, and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- SPL e-mail account (spl@fda.hhs.gov)